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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,707	09/30/2004	Jeffrey Lee Spray	B0368-US01	5706

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EXAMINER
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DANEGA, RENEE A

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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09/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/711,707	<b>Applicant(s)</b> SPRAY ET AL.	
	<b>Examiner</b> Renee Danega	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 and 26-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/15/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of claims 1-9 and 25 in the reply filed on 10/22/07 is acknowledged.

***Claim Objections***

2. Claims 5 and 25 are objected to because of the following informalities: Claim 5 refers to "said rigid connector" with no antecedent basis and claim 25 refers to "said biologically compatible receptacle" with no antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lynn (US 5167656).
  - Regarding claim 1, Lynn teaches a biologic fluid sampling device comprising a biologically compatible reservoir having an interior chamber (34) for receiving a biologic fluid, a fluid access port (32), and a fluid egress port (30), a needle (14) in fluid communication with said chamber through said fluid egress port (30), and a valve (44) interposed between

said chamber and said needle whereby flow of biologic fluid from said chamber through said needle may be selectively controlled (Figure 1).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn as applied to claim 1 above, and further in view of Danby et al (US 4725269).

- Regarding claims 2-4. Lynn teaches any known valve component can be used (column 25-28) but doesn't expressly teach specifics of the valve. However, Danby teaches a crimp valve assembly having a rigid base (4) and sidewall (2) supporting the valve and coupled to a reservoir area (interior of the device) with a central beam (216) extending generally linearly from the fluid egress port and capable of being coupled to a needle (212) and supporting it in a fixed relationship relative the reservoir (Figures 1 and 15) which uses a pinch valve for precise manual flow control (column 1, lines 10-15). It would have been obvious in view of Danby to provide a pinch valve clamping device in Lynn in order to provide precise manual flow control.
- Regarding claim 5, Danby's device has a flexible tube (208) extending along the central beam from said fluid egress port wherein said valve

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comprises an arm (28) pivotally (6) connected to said rigid connector and extending across the tube and central beam (when closed) such that said tube can be compressed (60) between said beam and said arm (Figures 2, 6).

- Regarding claims 6-7, Danby's arm has a fixed end (at hinge 6) and a moveable end (at 24) and said device further comprises a bracket or opposing latches (20, 22) mounted on said connector (4), said moveable end of said arm (28) being connected to said bracket (when closed) and a hinge mounted on said connector (6) (Figures 2, 6).
- Regarding claim 8, Danby's device comprises a ridge extending along said arm (point 28) configured to selectively press (60) against said tube (Figure 2).

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn as applied to claim 1 above, and further in view of Coburn (US 4932418).

- Lynn doesn't expressly teach a bottle adapter connected to the valve. However, Coburn teaches a bottle adapter (41) surrounding a needle (21) of a sampling device in order to fit the needle to a vial (35) or safely store the needle (55) (Figures 10-11). It would have been obvious in view of Coburn to provide a bottle adapter on the needle of Lynn to enable the needle to connect to vials securely or safely store the needle when not in use.

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8. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynn as applied to claim 1 above, and further in view of Richmond (US 6068617).

- Regarding claim 25, Lynn teaches a fluid product bag (12) and a tube (28) connecting the bag (12) to the fluid access port of the receptacle (32) but doesn't expressly teach how the bag and tube are connected (Figure 1). However, Yoshino teaches a tube (51) connecting to a bag (38) with a frangible valve (54) interposed in the tube to permit selective fluid access to a receptacle (20) (Figures 1, 2A-B). It would have been obvious in view of Lynn to one of ordinary skill in the art to provide the connection means of Richmond to secure the tubing to the fluid product bag.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736